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PATENT  
Docket No. R-237.00

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: )  
SCHEIFLINGER, *et al.* )  
Serial No.: 09/661,992 ) Art Unit: 1644  
Filed: September 14, 2000 )  
For: Factor IX/Factor IXa Activating ) Examiner: Haddad, Maher M.  
Antibodies and Antibody Derivatives )

**CERTIFICATE OF EXPRESS MAILING UNDER 37 CFR §1.10**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

I hereby certify that the following documents:

- 1) Information Disclosure Statement;
- 2) Form PTO-1449;
- 3) Copies of 48 cited references;
- 4) Copies of International Search Report; and
- 5) Post Card Receipt

are being deposited with the United States Postal Service as Express Mail, Label No. **EV201038232US** in an envelope addressed to: Commissioner for Patents, P. O. Box 1450, Alexandria, VA 22313-1450 on **November 14, 2003**.

Respectfully submitted,

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SCHEIFLINGER, et al.

Serial No. 09/661,992

Filed: September 14, 2000

For: Factor IX/Factor IXa Activating  
Antibodies and Antibody  
Derivatives

Art Unit: 1644

Examiner: Haddad, Maher M.

Atty. Docket: R-237.00

**Information Disclosure Statement**

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not

exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

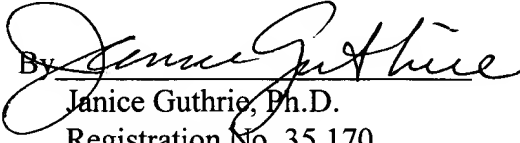
- ☒ 1. This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.
  - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
  - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
  - ☐ c. Attached is our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).

- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our Check No. \_\_\_\_\_ in the amount of \$ \_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☒ 4. The following document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application: WO95/13300, Nilsson et al. and Bajaj et al. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.
- ☐ 5. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 6. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

**The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 02-1437 (R-237.00).**

Respectfully submitted,

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<b>FORM PTO-1449 (Modified)</b>	Docket No.: R-237.00	Serial No.: 09/661,992
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT	Applicant: SCHEIFLINGER, et al.	
	Filed: September 14, 2000	Art Unit: 1644

## UNITED STATES PATENT DOCUMENTS

* Exr's. Init.	Ref.	Patent No.	Date	Name	Class	Sub	Filing Date (if applicable)
	AA	4,395,396	7/1983	Eibl et al.			
	AB	4,873,316	10/1989	Meade et al.			
	AC	5,932,706	8/1999	Mertens			

## FOREIGN PATENT DOCUMENTS

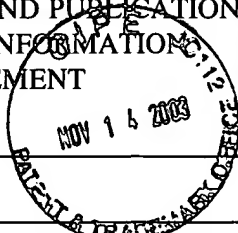
Exr's. Init.	Ref.	Document No.	Date	Country	Class	Sub	Translation?
							Yes No
	AD	WO95/13300	5/18/95	PCT			
	AE	WO97/26010	7/24/97	PCT			
	AF	WO99/01476	1/14/99	PCT			

## OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)

Exr's. Inits.	Ref.	Bibliographic Data
	AG	Ames, R.S. et al., <i>Conversion of Murine Fabs Isolated From a Combinatorial Phage Display Library to Full Length Immunoglobulins</i> , <u>J. Immunol. Methods</u> , pp. 177-186 (1995).
	AH	Bajaj, S.P. et al., <i>A Monoclonal Antibody to Factor IX That Inhibits the Factor VIII:Ca Potentiation of Factor X Activation</i> , <u>The Journal of Biological Chemistry</u> , 260(21), pp. 11574-11580 (1985).
	AI	Bessos, H., et al., <i>The Characterization of a Panel of Monoclonal Antibodies to Human Coagulation Factor IX</i> , <u>Thrombosis Research</u> , 40, pp. 863-867 (1985).
	AJ	Cao, Y. et al., <i>Bispecific Antibodies as Novel Bioconjugates</i> , <u>Bioconjugate Chemistry</u> , 9(6), pp. 635-644 (1998).
	AK	Cohen, F.E., et al., <i>The Combinatorial Approach, Protein Structure Prediction--A Practical Approach</i> (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 9, pp. 207-227 (1996).

Examiner	Date Considered
* Examiner: Initial if citation considered, whether or not citation is in conformance with M.P.E.P. ¶1609. Draw line through citation (i.e., citation) if not in conformance and not considered. Include copy of this form with next communication to applicant.	

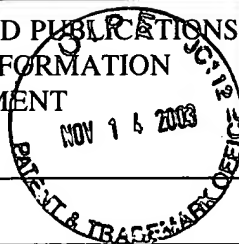
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OTHER REFERENCES (Including Author, Date, Title, Pertinent Pages, Etc.)		
Exr's. Inits.	Ref.	Bibliographic Data
	AL	Engelhardt, O., et al., <i>Two-Step Cloning of Antibody Variable Domains in a Phage Display Vector</i> , <u>Biotechniques</u> , 17, p. 44-46 (1994).
	AM	Esser, C., et al., <i>Immunoglobulin Class Switching: Molecular and Cellular Analysis</i> , <u>Annu. Rev. Immunol.</u> , 8, p. 717-735 (1990).
	AN	Evan, G.I., et al., <i>Isolation of Monoclonal Antibodies Specific for Human c-myc Proto-Oncogene Product</i> , <u>Mol. Cell. Biol.</u> , 5(12), p. 3610-3616 (1985).
	AO	Fay, P.J., et al., <i>Factor VIIIa A2 Subunit Residues 558-565 Represent a Factor IXa Interactive Site</i> , <u>Journal of Biological Chemistry</u> , 269(32), p. 20522-20527 (1994).
	AP	Frazier, D., et al., <i>Mapping of Monoclonal Antibodies to Human Factor IX</i> , <u>Blood</u> , 74(3), p. 971-977 (1989).
	AQ	Gao, C., et al., <i>Making Artificial Antibodies: A Format for Phage Display of Combinatorial Heterodimeric Arrays</i> , <u>Proc. Natl. Acad. Sci.</u> , 96, p. 6025-6030 (1999).
	AR	Grassy, G., et al., <i>Computer-Assisted Rational Design of Immunosuppressive Compounds</i> , <u>Nature Biotechnology</u> , 16, p. 748-752 (1998).
	AS	Greer, J., et al., <i>Application of the Three-Dimensional Structures of Protein Target Molecules in Structure-Based Drug Design</i> , <u>Journal of Medicinal Chemistry</u> , 37(8), p. 1035-1054 (1994).
	AT	Harlow, E., et al., 2. <i>Antibody Molecules</i> , <u>Antibodies--A Laboratory Manual</u> ; pp. 7-22 (1988).
	AU	Harlow, E., et al., 3. <i>Antibody-Antigen Interactions</i> , <u>Antibodies--A Laboratory Manual</u> ; p. 23-35 (1988).
	AV	Harlow, E., et al., 6. <i>Monoclonal Antibodies</i> , <u>Antibodies--A Laboratory Manual</u> ; p. 139-243 (1988).
	AW	Hochuli, E., et al., <i>Genetic Approach to Facilitate Purification of Recombinant Proteins with a Novel Metal Chelate Adsorbent</i> , <u>Biotechnology</u> , 6, p. 1321-1325 (1988).
	AX	Huston, J.S., et al., <i>Medical Applications of Single-Chain Antibodies</i> , <u>Intern. Rev. Immunol.</u> , 10, p. 195-217 (1993).
	AY	Jones, D.T., et al., <i>Protein Folds and Their Recognition from Sequence</i> , <u>Protein Structure Prediction--A Practical Approach</u> (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 8, p. 174-206 (1996).

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Exr's. Inits.	Ref.	Bibliographic Data
	AZ	Jones, P.T., et al., <i>Replacing the Complementarity-Determining Regions in a Human Antibody with Those from a Mouse</i> , <u>Nature</u> , 321, p. 522-525 (1986).
	BA	Jorquera, J.I., et al., <i>Synthetic Peptides Derived from Residues 698 to 710 of Factor VIII Inhibit Factor IXa Activity</i> , <u>Circulation</u> , 86, Abstract No. 2725, p. I-685 (1992).
	BB	Karpen, M.E., et al., <i>Modelling Protein Conformation by Molecular Mechanics and Dynamics, Protein Structure Prediction--A Practical Approach</i> (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 10, p. 229-261 (1996).
	BC	Kemp, D.S., <i>Peptidomimetics and the Template Approach to Nucleation of B-sheets and a-helices in Peptides</i> , <u>TIBTECH</u> , 8, p. 249-255 (1990).
	BD	Kerschbaumer, R.J., et al, <i>pDAP2: A Vector for Construction of Alkaline Phosphatase Fusion-Proteins</i> , <u>Immunotechnology</u> , 2, p. 145-150 (1996).
	BE	Kerschbaumer, R.J. et al., <i>Single-Chain Fv Fusion Proteins Suitable as Coating and Detecting Reagents in a Double Antibody Sandwich Enzyme-Linked Immunosorbent Assay</i> , <u>Analytical Biochemistry</u> , 249, p. 219-227 (1997).
	BF	Lane, R.D., <i>A Short-Duration Polyethylene Glycol Fusion Technique for Increasing Production of Monoclonal Antibody-Secreting Hybridomas</i> , <u>Journal of Immunological Methods</u> , 81, p. 223-227 (1985).
	BG	Lenting, P.J., et al., <i>The Sequence Glu<sup>1811</sup>-Lys<sup>1818</sup> of Human Blood Coagulation Factor VIII Comprises a Binding Site for Activated Factor IX</i> , <u>Journal of Biological Chemistry</u> , 271(4), p. 1935-1940 (1996).
	BH	Liles, D.K., et al, <i>The Factor VIII Peptide Consisting of Amino Acids 698 to 712 Enhances Factor IXa Cleavage of Factor X</i> , <u>Blood</u> , 90(1), Abstract No. 2054, p. 463a (1997).
	BI	Lin, H-F., et al, <i>A Coagulation Factor IX-Deficient Mouse Model for Human Hemophilia B</i> , <u>Blood</u> , 90(10), p. 3962-3966 (1997).
	BJ	Malik, P., et al., <i>Multiple Display of Foreign Peptide Epitopes on Filamentous Bacteriophage Virions</i> , <u>Phage Display of Peptides and Proteins</u> (Ed. B. K. Kay et al.), Academic Press, p. 127-139 (1996).
	BK	Mann, K.G., et al., <i>Surface-Dependent Reactions of the Vitamin K-Dependent Enzyme Complexes</i> , <u>Blood</u> , 76(1), p. 1-16 (1990).

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	BL	Mikaelsson, M., et al., <i>Standardization of VIII:C Assays: A Manufacturer's View</i> , <i>Scandinavian Journal of Haematology</i> (Ed. Nilsson et al.), 33, p. 79-86 (1984).
	BM	Nilsson, I.M. et al., <i>Induction of Split Tolerance and Clinical Cure in High-Responding Hemophiliacs with Factor IX Antibodies</i> , <i>Proc. Natl. Acad. Sci. USA</i> , 83, p. 9169-9173 (1986).
	BN	Persic, L., et al., <i>An Integrated Vector System For The Eukaryotic Expression of Antibodies or Their Fragments After Selection From Phase Display Libraries</i> , <i>Gene</i> , p. 9-18 (1997).
	BO	Pluckthun, A., et al., <i>New Protein Engineering Approaches to Multivalent and Bispecific Antibody Fragments</i> , <i>Immunotechnology</i> , 3, p. 83-105 (1997).
	BP	Raag, R., et al., <i>Single-Chain Fvs</i> , <i>FASEB Journal</i> , 9(1), pp. 73-80 (1995).
	BQ	Rees, A.R., et al., <i>Antibody Combining Sites: Structure and Prediction</i> , <i>Protein Structure Prediction--A Practical Approach</i> (Ed. M.J.E. Sternberg), Oxford University Press, Ch. 7, p. 141-172 (1996).
	BR	Roitt, I.M., et al., <i>Molecules which Recognize Antigen</i> , <i>Immunology</i> , 2 <sup>nd</sup> Edition, p. 5.1-5.11 (1989).
	BS	Sadler, J.E., et al., <i>Hemophilia A, Hemophilia B, and von Willebrand's Disease</i> , <i>The Molecular Basis of Blood Diseases</i> (Ed. G. Stamatoyannopoulos et al.), p. 575-630 (1987).
	BT	Vaughan, T.J., et al., <i>Human Antibodies By Design</i> , <i>Nature Biotechnology</i> , p. 535-539 (1998).
	BU	Winter, G., et al., <i>Making Antibodies by Phage Display Technology</i> , <i>Annu. Rev. Immunol.</i> , 12, p. 433-455 (1994).
	BV	Zhong, D., et al., <i>Some Human Inhibitor Antibodies Interfere with Factor VIII Binding to Factor IX</i> , <i>Blood</i> , 92(1), p. 136-142 (1998).

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